IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DUKE UNIVERSITY, ALLERGAN, INC., and ALLERGAN SALES, LLC, Plaintiffs, v. AKORN, INC., and HI-TECH PHARMACAL CO., INC., Defendants.	Civil Action No. 3:18-14035

AKORN'S OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS AKORN'S COUNTERCLAIMS AND STRIKE RELATED AFFIRMATIVE DEFENSES, OR ALTERNATIVELY, BIFURCATE AND STAY

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I. INTRODUCTION

This is the latest in a series of patent litigations asserted by Allergan, Inc., and Allergan Sales, LLC (collectively, "Allergan"), and its co-conspirator Duke University ("Duke") (collectively, "Plaintiffs"), against Akorn, Inc., and Hi-Tech Pharmacal Co., Inc. (collectively, "Akorn") concerning Akorn's efforts to gain patent clearance for its proposed generic bimatoprost product. Over the past eight years, Plaintiffs have experienced failure after failure to successfully litigate a single patent claim against Akorn. And yet, Plaintiffs have repeatedly ignored the prior court decisions invalidating their patents and have continued to assert substantially similar patent claims against Akorn in an attempt to protect Plaintiffs' market share. Now, Plaintiffs have asserted an eighth patent, which is substantially similar to the previously invalidated patents and must be similarly held invalid under collateral estoppel. In response to Plaintiffs' most recent action in its anticompetitive scheme, Akorn has alleged certain counterclaims against Plaintiffs, including: actual monopolization based on sham litigation (Fourth and Fifth Counterclaims); attempted monopolization (Sixth Counterclaim); Conspiracy to Monopolize (Seventh Counterclaim), and Patent Misuse (Eighth Counterclaim) (collectively "Akorn's Antitrust and Misuse Counterclaims").

Plaintiffs now add a battery of meritless motions to its serial use of invalid patents in an attempt to further delay resolution of the matter and prevent Akorn's ANDA Product from entering the market. First, Plaintiffs ask to dismiss Akorn's Antitrust and Misuse Counterclaims under Fed. R. Civ. P. 12(b)(6). Second, Plaintiffs ask to dismiss Akorn's corresponding Antitrust and Misuse Affirmative Defenses (Akorn's Seventh, Eighth, and Ninth Affirmative Defenses) under Fed. R. Civ. P. 12(f). Third, Plaintiffs ask, in the alternative, to bifurcate and stay discovery of Akorn's Antitrust and Misuse Counterclaims and Defenses pending the outcome of

Plaintiffs' patent infringement lawsuit. None of Plaintiffs' requests are appropriate here, particularly at this early stage of litigation.

Akorn has pled facts showing that Plaintiffs' current litigation has no reasonable basis; Plaintiffs assert patent claims for which very nearly identical claims from closely related patents were first invalidated by the Federal Circuit nearly 5 years ago and collateral estoppel will attach. This is not Plaintiffs' first attempt to relitigate the invalidated patents of *Latisse I*. Allergan was ordered collaterally estopped from enforcing related patents against Akorn in *Latisse II* and *III*, based on the Federal Circuit's holding in *Latisse I*. Based on this series of activities, Plaintiffs have engaged in objectively baseless sham litigation. To date, Akorn has received patent clearance in three separate cases, but Plaintiffs continue to misuse the courts to assert clearly invalid patents to cause delay. Each day that resolution is further delayed inhibits Akorn's ability to market its proposed generic product and provides financial benefits to Plaintiffs by preserving its market share through government petition instead of competition.

For the reasons set forth herein, Akorn respectfully requests this Court deny each of Plaintiffs' motions.

II. BACKGROUND

A. Parties in Suit and Bimatoprost Ophthalmic Solution, 0.03%

The instant litigation is the fourth in a series of patent litigations ongoing since 2011, all concerning Akorn's Abbreviated New Drug Application ("ANDA") No. 20-3051 for bimatoprost ophthalmic solution, 0.03%. (Akorn's Answer, Affirmative Defenses, and Counterclaims, D.I. 8 ("Akorn's Countercl.") at ¶¶ 33-51.)

Allergan, Inc. is the holder of New Drug Application ("NDA") No. 22-369 for bimatoprost ophthalmic solution, 0.03%, which is sold in the United States by Plaintiff Allergan Sales, LLC under the brand name LATISSE®. (*Id.* at ¶¶ 26-27.) Latisse is FDA approved to

treat hypotrichosis of the eyelashes by increasing their growth, including length, thickness, and darkness. (*Id.* at ¶ 29.)

In 2007, Allergan entered into an license agreement with Duke University, where Duke exclusively licensed certain Duke patents to Allergan in exchange for a non-refundable, non-creditable running royalty of 2% on net sales of LATISSE®, gave Allergan the right to prosecute patent infringement lawsuits for the licensed patents, and agreed to join the patent lawsuits as a necessary party, without regard to the merits of any particular lawsuit. (*Id.* at ¶¶ 202-08.) The amount of royalties Duke receives from Allergan relating to the sale of LATISSE® is directly proportional to the net sales of LATISSE®. (*Id.* at ¶ 204.)

Akorn is a pharmaceutical company and the current holder of ANDA No. 20-3051 ("Akorn's ANDA"), which is an FDA-approved generic version of LATISSE®. (*Id.* at ¶ 23.) Akorn's ANDA was originally filed by Hi-Tech Pharmacal ("Hi-Tech"), which was acquired by Akorn in 2014.[1] (*Id.* at ¶ 24.) Despite FDA approval of Akorn's ANDA No. 203051 in October 2018, Akorn has not yet commercially launched its product. (*Id.* at ¶ 25.)

B. Procedural History and History of Asserted Patents

Since 2011, Allergan has brought four suits against Akorn, alleging infringement of patents directed to LATISSE® by Akorn's proposed ANDA product, and Duke has joined three of these suits. (*Id.* at ¶¶ 2, 34, 39, 44); *Allergan, Inc. et al. v. Hi-Tech Pharmacal Co., Inc.* NCMD-1-11-cv-00650 at D.I. 1 (litigation hereinafter referred to as "*Latisse I*"); *Allergan, Inc. v. Apotex Inc. et al.*, No. 1:12-cv-247 at D.I. 1; 1:13-cv-16 at D.I. 1 (litigation hereinafter referred to as "*Latisse II*"); *Allergan, Inc. v. Sandoz, Inc. et al.*, No. 1:14-cv-1034 at D.I. 1, 15 (litigation

[1] For purposes of this brief, Akorn and Hi-Tech will be treated interchangeably and as a single entity. But Hi-Tech developed the product and filed the ANDA before the Akorn acquisition.

hereinafter referred to as "*Latisse III*"); *Duke University et al. v. Akorn, Inc. et al.*, No. 3:13-14034, D.I. 1 (litigation hereinafter referred to as "*Latisse IV*").

Through these four suits, Plaintiffs have asserted substantially similar claims of eight total patents. (Akorn's Countercl. at ¶¶ 34, 39, 40, 44, 48.) Of the seven patents asserted in *Latisse I – III*, Plaintiffs failed to establish infringement of a single valid patent claim. (*Id.* at ¶¶ 38, 43, 49.) A chart of the asserted patents is set forth below:

Patent	Relationship	Litigation	Disposition of
U.S. Patent No. 7,351,404 ("'404 patent")		*Latisse I*	Invalid as obvious
U.S. Patent No. 7,388,029 ("'029 patent")		*Latisse I*	Invalid as obvious
U.S. Patent No. 8,038,988 ("'988 patent")	Continuation of '404 patent	*Latisse II*	Invalid as obvious/barred by collateral estoppel
U.S. Patent No. 8,101,161 ("'161 patent")	Continuation of '404 patent	*Latisse II*	Invalid as obvious/barred by collateral estoppel
U.S. Patent No. 8,263,054 ("'054 patent")	Continuation of '404 patent	*Latisse II*	Invalid as obvious/barred by collateral estoppel
U.S. Patent No. 8,906,962 ("'962 patent")	Continuation of '029 patent	*Latisse III*	Voluntarily dismissed
U.S. Patent No. 8,926,953 ("'953 patent")	Continuation of '404 patent	*Latisse III*	Invalid as obvious/barred by collateral estoppel
U.S. Patent No. 9,579,270 ("'270 patent")	Continuation of '029 patent	*Latisse IV*	Pending

C. Allergan's and Duke's Pursuit of Sham Litigations

1. Latisse I

In 2011, Allergan, Inc. and Duke University filed a Complaint against Hi-Tech and other ANDA filers, claiming *inter alia* that Akorn's ANDA infringed the '404 patent and the '029 patent. (*Id.* at ¶ 34.) Both patents are generally directed to use of a broad class of prostaglandins to alter hair growth. (*Id.* at ¶ 36.) Of the two, the '029 patent is licensed to Allergan by Duke.

(*Id.* at ¶ 202.) Although the district court initially sided with Plaintiffs, the Federal Circuit reversed in 2014, holding the '029 and '404 patents invalid as obvious. (*Id.* at ¶¶ 35-36.) The Federal Circuit held that it would have been obvious to use the family of compounds that includes bimatoprost to treat hair loss. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 962-66 (Fed. Cir. 2014) (*Latisse I*); *see also Allergan*, 681 Fed. App'x. at 960-61 n.5 (*Latisse III*) ("We previously found in [*Latisse I*] that it would have been obvious to use a topical application of a bimatoprost composition to grow eyelashes.").

In its opinion, the Federal Circuit identified two specific errors in the district court's initial conclusion that the '029 patent was non-obvious. *See Allergan*, 754 F.3d at 962-66 (*Latisse I*). First, the Federal Circuit found the district court failed to consider the appropriate scope of the '029 patent's asserted claims, which included "thousands of permutations of synthetic [prostaglandin F-2-alpha ("PGF")] analogs," and not just bimatoprost, which is only one such analog. *Id.* at 962. Second, the Federal Circuit found clear error in the district court "taking an overly cramped view of what the prior art teaches." *Id.* at 963. The Federal Circuit explicitly found the patent claims obvious over PCT Application No. PCT/US98/02289 ("Johnstone") in view of U.S. Patent No. 5,688,819 ("the '819 patent"), noting that, "there was nothing left for a chemist to do[, as] Johnstone taught squarely towards a new utility for a finite set of already identified and isolated compounds with properties that had already been characterized." *Id.* at 964. Therefore, because the Johnstone prior art reference "taught that PGF analogs" such as bimatoprost, "could be used to grow hair," all aspects of the entire '029 patent were obvious and therefore the asserted patent claims were invalid. *Id.* at 965.

2. Latisse II

While Latisse I was pending, Allergan filed two additional lawsuits asserting three additional patents against several defendants, including Akorn, which were consolidated into

Latisse II. (Akorn's Countercl. at ¶ 39.) Each of the '988, '161, and '054 patents asserted in *Latisse II* were continuations of the '404 patent invalidated in *Latisse I*. (*Id.* at ¶ 40.) A continuation patent shares the same specification and priority date of invention as the parent patent and cannot add any new matter not found in the parent. Shortly after issuance of the Federal Circuit opinion in *Latisse I*, the district court held that Allergan, Inc. was collaterally estopped from asserting or contesting the invalidity of the '988, '161, and '054 patents in light of the Federal Circuit's finding of invalidity of the related '404 patent. (*Id.* at ¶ 41.) Allergan did not appeal. (*Id.* at ¶ 43.)

3. Latisse III

After the Federal Circuit's invalidating decision in *Latisse I* issued, Allergan, Inc. and Duke filed yet another lawsuit against Akorn alleging Akorn's ANDA product infringed two new patents. (*Id.* at ¶¶ 44, 47, 49.) The asserted '962 patent was a continuation of the invalidated '404 patent and the asserted '953 patent was a continuation of the invalidated '029 patent. Allergan Inc. and Duke ultimately decided to drop assertion of the '962 patent, but continued to litigate the '953 patent. (*Id.* at ¶ 45.) Both the district court and the Federal Circuit held that Allergan was collaterally estopped from asserting or contesting validity of the '952 patent based on *Latisse I* and *II*. (*Id.* at ¶ 50.) In explaining its holding, the district court noted that the '953 patent "claims priority to, and [recites] substantially the same subject matter as, invalid '404 patent claim 14 [which had been invalidated in Latisse I] and the relevant claims of the '054, '161, and '988 patents [which had been invalidated in Latisse II]." *Latisse III* at Dkt. No. 72, p. 2.

4. Latisse IV

Plaintiffs filed the present action against Akorn on September 19, 2018, again alleging that Akorn's ANDA product infringes a newly-issued LATISSE® patent that is a continuation

from the same flawed family. As admitted by Plaintiffs, "the [newly asserted] '270 patent claims priority to the application that led to the '029 patent invalidated in *Latisse I*." (Plaintiffs' Memorandum of Law in Support of Their Motion to Dismiss Akorn's Antitrust and Patent Misuse Counterclaims and to Strike Related Affirmative Defenses, or Alternatively, to Bifurcate and Stay Akorn's Antitrust and Patent Misuse Counterclaims and Related Affirmative Defenses, D.I. 22 ("Pl.'s Br.") at 7.) The asserted claims 22 and 30 of the '270 patent are substantially similar to numerous claims that were previously invalidated as obvious in *Latisse I*. (*Id.* at ¶ 58.) For example, just like the previously invalidated claim, the '270 patent claims generally relate to methods of enhancing hair growth using prostaglandins. (*Id.* at ¶ 59.) Plaintiffs incorrectly allege that the '270 patent can be distinguished from the '029 patent as "limited significantly," and willfully ignore the holding of the Federal Circuit in *Latisse I* that the '029 patent was invalidated as obvious in light of the prior art, and not solely due to the scope of the '029 patent. *Allergan*, 754 F.3d at 965-66 (*Latisse I*). Even assuming arguendo that Plaintiffs' characterization of the Federal Circuit's opinion was correct—which it is not—Plaintiffs' attempt to manipulate its patent applications to address a single, non-dispositive issue identified by the Federal Circuit cannot save it from obviousness.

In response to Plaintiffs' serial filings of sham litigations for purported patent infringement, Akorn asserted antitrust and patent misuse Counterclaims against Plaintiffs, including: actual monopolization based on sham litigation (Counts IV and V); attempted monopolization (Count VI); Conspiracy to Monopolize (Count VII), and Patent Misuse (VIII). (Akorn's Countercl. at ¶¶ 127-238.)

III. STANDARD OF REVIEW

A. Rule 12(b)(6) Motion to Dismiss Standard of Review

A motion to dismiss should be granted only if the complaint fails to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the complaint must contain sufficient factual allegations to "raise a right to relief above the speculative level." *Id.* at 555. In light of *Twombly*, the Third Circuit has held that "[i]t remains an acceptable statement of the standard, for example that courts 'accept all factual allegations as true, construe the complaint in the light most favorable to the [claimant], and determine whether, under any reasonable reading of the complaint, the [claimant] may be entitled to relief'." *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (citations omitted). "Although a court does not need to credit bald assertions or legal conclusions, it must view all of the allegations in the counterclaim as well as all reasonable inferences that can be drawn therefrom in the light most favorable to the counterclaimant." *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 346 (D.N.J. 2009) (internal citations and quotations omitted). Therefore, the issue before the court "is not whether a [claimant] will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997). The same standards are applied to a court's analysis of the sufficiency of counterclaims. *See e.g.*, *Organon Inc. v. Mylan Pharmaceuticals, Inc.*, 293 F. Supp. 2d 453, 456-57 (D.N.J. 2003).

B. Rule 12(f) Motion To Dismiss Standard of Review

Striking an affirmative defense is "a drastic remedy, to be resorted to only when required for the purposes of justice." *In re Gabapentin*, 649 F. Supp. 2d at 346. "Generally, motions to strike are highly disfavored." *U.S. v. Boston Scientific Neuromodulation Corp.*, No. 2:11-cv-1210, 2014 WL 4402118, at *3 (D.N.J. Sep. 4, 2014). To survive a motion to dismiss filed under

Rule 12(f), the "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true," even if doubtful in fact. *Twombly*, 550 U.S. at 545. Third Circuit law holds "[t]his does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *In re Gabapentin*, 649 F. Supp. 2d at 346 (citing *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008)).

C. Bifurcation Standard of Review

There is no routine order regarding bifurcation within the Third Circuit. *See Lis v. Robert Packer Hospital*, 579 F.2d 819, 824 (3d Cir. 1978). When considering whether to bifurcate a trial, "the decision to bifurcate *vel non* is a matter to be decided on a case-by-case basis and must be subject to an informed discretion by the trial judge in each instance." *Id.* (citing *Idzojtic v. Pennsylvania Railroad Co.*, 456 F.2d 1228, 1230 (3d Cir. 1971)). "The party moving for bifurcation has the burden of showing that bifurcation is proper in light of the general principle that a single trial tends to lessen the delay, expense and inconvenience to all parties." *Huertas v. Transunion, et al.*, No. 08-2009-JBS-JS, 2009 WL 10697260 (D.N.J. Apr. 29, 2009) (citing *Miller v. New Jersey Transit Authority Rail Operations*, 160 F.R.D. 37, 40 (D.N.J. 1995)).

IV. THE COURT SHOULD DENY PLAINTIFFS' MOTION TO DISMISS

Sham litigations are excluded from the protection of the *Noerr-Pennington* doctrine, and thus are not shielded from antitrust scrutiny. *See Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 178 (3d Cir. 2015); *see also In re Gabapentin*, 649 F. Supp. 2d at 361 (citing *Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)). Thus at the motion to dismiss stage, it is Akorn's burden to plead sufficient factual allegations to "raise a right of relief above the speculative level" that Plaintiffs have engaged in

sham litigation. *See Twombly*, 550 U.S. at 555. Akorn has met this burden, and has set forth ample facts in its counterclaims to support its claims that Plaintiffs have engaged in both a single and series of sham litigations.

Within the Third Circuit, "the existence of antitrust injury is not typically resolved through motions to dismiss." *In re Gabapentin*, 649 F. Supp. 2d at 355. To the contrary, "[a]ntitrust complaints, in particular, are to be liberally construed" during the pleadings stage. *Id.* at 347. "In antitrust cases, where the proof is largely in the hands of the alleged conspirators, dismissals prior to giving the [claimant] ample opportunity for discovery should be granted very sparingly. The liberal approach to the consideration of antitrust complaints is important because inherent in such an action is the fact that all details and specific facts relied upon cannot properly be set forth as part of the pleadings." *Id.* (internal citations and quotations omitted).

Plaintiffs' briefing focuses largely on attacking the merits of Akorn's counterclaims and ignores its own high burden to support its motion to dismiss. Notably, Plaintiffs do not appear to challenge the sufficiency of Akorn's actual or attempted monopoly counterclaims regarding any element except for the establishment of sham litigation. As further discussed below, Akorn has alleged ample facts to support its antitrust and patent misuse counterclaims, including the sham litigation and series of sham litigations. Moreover, Akorn expects that additional facts to support its counterclaims will be uncovered through fact discovery.

A. Plaintiffs Do Not Challenge the Majority of Elements Required To Establish Akorn's Actual or Attempted Monopolization Counterclaims

As a preliminary matter, Plaintiffs ask the Court to dismiss Akorn's Fourth and Fifth Counterclaims for Actual Monopolization and Sixth Counterclaim for Attempted

Monopolization only because Akorn has not sufficiently pleaded a sham litigation.[2] Plaintiffs concede that Akorn's pleadings sufficiently detail the relevant market (Akorn's Countercl. at ¶¶ 74-75), establish Plaintiffs market power (*id.* at ¶¶ 76-87), identify antitrust injury (*id.* ¶¶ at 162-169, ¶¶ 179-186, ¶¶ 194-200, ¶¶ 213-219.) Moreover, Plaintiffs also do not challenge the allegations that Allergan has engaged in actual monopolization, has attempted monopolization, and that Plaintiffs have conspired to monopolize the relevant market of FDA-approved treatments for hypotrichosis of eyelashes. (Pl.'s Br. at 18-20.) Akorn's allegations are sufficiently pleaded, and Plaintiffs' motion should be denied.

B. Akorn Has Sufficiently Pled That Plaintiffs' Have Pursued a Series Of Sham Litigations

Plaintiffs ask the Court to dismiss Akorn's Fifth Counterclaim and the portion of Akorn's Sixth Counterclaim directed to harm caused by Plaintiffs' series of sham litigations, by ignoring the well-pleaded allegations of Akorn's counterclaims and using an incorrect legal standard. The Court should deny Plaintiffs' motion.

When evaluating whether a series or pattern of lawsuits are sufficient to establish a series of sham litigations, the relevant inquiry is "whether a series of petitions were filed with or without regard to merit and for the purpose of using the government process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Hanover*, 806 F.3d at 180 (adopting the standard set forth in *Cal. Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972)). Importantly, "the question is not whether any one of them has merit—some may turn out to, just as a matter of chance—but whether they are brought pursuant to a policy of starting

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[2] Akorn's Fourth Counterclaim is directed to Actual Monopolization for a single sham litigation; Akorn's Fifth Counterclaims is directed to Actual Monopolization for a series of sham litigations; and Akorn's Sixth Counterclaim is directed to Attempted Monopolization on the basis of either a series of sham litigation or a single sham litigation.

legal proceedings without regard to the merits and for the purpose of injuring a market rival." *Id.* at 198. The Third Circuit has consistently applied this *California Motor* test in cases where a party or group of parties is accused of repeatedly filing serial litigation against a defendant. *See, e.g.*, *id.* at 180 ("when a party alleges a series of legal proceedings, we conclude that the sham litigation standard from California Motor should govern."); *see also In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 157 (3d Cir. 2017).

1. Akorn's factual allegations sufficiently plead a series of sham litigations

Akorn has pled sufficient facts to show that Plaintiffs' have pursued a series of sham litigations, culminating in the present action. These facts include:

- ¶ 130: "Allergan, Inc. and/or Allergan Sales have sued Akorn four times for patent infringement relating to the same product: Akorn's Proposed ANDA Product."
- ¶ 131: "Duke has sued Akorn three times for patent infringement relating to the same product: Akorn's Proposed ANDA Product."
- ¶ 116: "Hi-Tech, Duke, and Allergan, Inc. completely litigated the issue of obviousness of the asserted claims of the '029 and '404 patents in Latisse I from the district court through appeal."
- ¶ 135 "Claims 22 and 30 of the '270 patent are substantially similar to, at least, Claims 1, 8, 14, 18, and 20 of the '029 patent and Claim 14 of the '404 patent, which were previously invalidated as obvious in *Latisse I*. Additionally, the '029 and '270 patents are related and share the same parent application."
- ¶ 146: "At least by September 19, 2018, Plaintiffs/Counterclaim-Defendants were aware that the '270 patent is related and claims priority to the '029 patent."
- ¶ 121: "The Federal Circuit in *Latisse I* held that the asserted claims of the '029 patent were invalid as obvious."
- ¶ 147: "At least by September 19, 2018, Plaintiffs/Counterclaim-Defendants were aware that certain claims of the '029 patent had been found invalid."
- ¶ 149: "At least by September 19, 2018, Plaintiffs/Counterclaim-Defendants were aware that Claims 22 and 30 of the '270 patent were substantially similar to the claims invalidated during the prior Latisse litigations, including Claim 1 of the '029 patent."

- ¶107: "Claims 22 and 30 of the '270 patent are prima facie obvious over the same prior art that formed the basis of invalidity of asserted claims of the '029 patent in Latisse I."

- ¶ 112: "Like the previously invalidated claims, 22 and 30 of the '270 patent encompass many different compositions."

- ¶ 125: "Plaintiffs/Counterclaim-Defendants are precluded from challenging the invalidity of Claims 22 and 30 of the '270 patent based on collateral estoppel.'

- ¶ 126: "Plaintiffs/Counterclaim-Defendants are precluded from asserting infringement of Claims 22 and 30 of the '270 patent against Akorn based on collateral estoppel."

- ¶ 134: "The current lawsuit was brought as part of an anticompetitive scheme to prevent Akorn and other potential competitors from launching their product, in order to prevent and delay competition."

- ¶ 150: "At least by September 19, 2018, Plaintiffs/Counterclaim-Defendants were aware that Akorn could sell its Proposed ANDA Product in the US upon receiving approval from the FDA."

- ¶ 151: "Allergan, Inc. and Allergan Sales were motivated to interfere with Akorn's potential sale of Akorn's Proposed ANDA Product to prevent competition in the relevant market."

- ¶ 152: "Duke was motivated to interfere with Akorn's potential sale of Akorn's Proposed ANDA Product based on a concern that such a sale could result in a reduction of Duke's royalties, which are proportional to Allergan's profits."

- ¶ 153: "In light of the acts described above, Plaintiffs/Counterclaim-Defendants' current Complaint was not made not out of a genuine interest in redressing grievances."

- ¶ 157: "A reasonable litigant would expect Claims 22 and 30 of the '270 patent to be invalid as obvious in light of this Court's findings in *Latisse I*, *Latisse II*, and *Latisse III*, as detailed above."

- ¶ 161: "Plaintiffs/Counterclaim-Defendants Duke filed the current Complaint with the subjective motivation of interfering directly with the business relationships of Akorn, a competitor."

Under the series test, circumstantial evidence of a party's motivations to engage in sham litigation is relevant to establish antitrust liability. *Hanover*, 806 F.3d at 180. Here, Akorn has pled sufficient facts to assert that the existence of the serial litigations is circumstantial evidence

that supports liability under the *California Motor* standard. Thus, Plaintiffs' accusation that Akorn's allegations contain only conclusory assertions (Pl.'s Br. at 10) has no merit.

Moreover, relevant circumstantial evidence includes the accused party's filing success, i.e. "win-loss percentage." *Hanover*, 806 F.3d at 180. In other words, unsuccessful lawsuits can serve as circumstantial evidence of Plaintiffs' intent in filing them. "A high percentage of meritless or objectively baseless proceedings . . . will tend to support a finding that the filings were not brought to redress any actual grievances." *Hanover*, 806 F.3d at 181. To date, Plaintiffs have either lost or withdrawn every single patent asserted against Akorn in the prior litigations. (Akorn's Countercl. at ¶¶ 38, 41, 47, 49.) The 100% "loss" rate by Plaintiffs thus weighs heavily in Akorn's favor. *See Hanover*, 806 F.3d at 180-81.

Plaintiffs incorrectly claim that "there can be no sham if more than an insignificant number of filings have objective merit." (Pl.'s Br. at 17 (citing *Hanover*, 806 F.3d 162).) Despite the misleading use of quotation marks in Plaintiffs' brief, *Hanover* does not suggest that such facts are dispositive. *See* 806 F.3d at 180 ("[E]ven if a small number of the petitions turn out to have some objective merit, that should not automatically immunize defendants from liability."). Regardless, Plaintiffs' own "win-loss percentage" serves only to bolster Akorn's sham litigation counterclaims because Plaintiffs have yet to prevail on any claim.

As set forth above and in Akorn's pleadings, Akorn has sufficiently pled direct and circumstantial facts to support a finding of a series of sham litigations. At most, Plaintiffs have raised questions of fact regarding the ultimate merits of the case, which may be properly evaluated further through discovery. Thus, this Court should deny Plaintiffs' motion to dismiss Akorn's Fifth and Sixth Counterclaim for monopolization and attempted monopolization through a series of sham litigations.

2. Plaintiffs attempt to impute an erroneous legal standard to evaluate the series of sham litigations

Plaintiffs incorrectly argue that the series test is not applicable in the instant matter because this is a Hatch-Waxman Act and the number of lawsuits at issue is too low. (Pl.'s Br. at 16-17.) Neither argument is persuasive, nor is it supported by the law. Moreover, both rely solely on Plaintiffs' own factual arguments. Under this faulty logic, Plaintiffs erroneously state that Akorn does not allege *Latisse I-III* were sham litigations. To the contrary, Akorn has sufficiently pled this under the appropriate legal standard. At the motion to dismiss stage, the Court must evaluate these facts in Akorn's favor.

In short, Plaintiffs attempt to argue that there can never be a series of sham litigations if the matter involves Hatch-Waxman litigation. (*Id.*) Plaintiffs cite no case law establishing this broadly prohibitive principle, instead citing only to one Third Circuit case in which the court did not find serial petitioning under the specific facts of that case. (*Id.*) Notably, the dispute in *Wellbutrin* concerned multiple lawsuits brought at a single time against different generic companies. Here, in contrast, Plaintiffs have filed multiple lawsuits against Akorn, asserting numerous substantially similar patents, one after another, despite prior invalidation and a court ruling of collateral estoppel. The Hatch-Waxman discussion in *Wellbutrin* cited by Plaintiffs in no way forecloses the application of the *California Motor* test to Hatch-Waxman cases. To the contrary, the *Wellbutrin* court explained that the *California Motor* test, as applied in *Hanover*, applies to "a series of legal proceedings" and not near-simultaneous proceedings against independent defendants. *Wellbutrin*, 868 F.3d at 157-58. Correspondingly, the *Wellbutrin* court evaluated and addressed only this form of simultaneous litigation, and not the type of serial litigation occurring here. *Id.* Additionally, the court noted that the number of lawsuit in a Hatch-Waxman litigation is often "dependent on the number of generic companies attempting to enter

the . . . market place, a matter over which [Plaintiffs have] no control." *Id.* at 158. Here, the choice to file serial litigations is wholly within Plaintiffs' control, and thus should be evaluated under the *California Motor* test. Akorn has now faced four successive, complex, and expensive patent infringement lawsuits involving eight related patents over a period of nearly eight years. The Hatch-Waxman Act was designed to promote efficient litigation and resolution of these patents. Plaintiffs cannot now hide behind the alleged intent of the Hatch-Waxman Act to create additional delay. Doing so is a clear example of the type of sham litigation prohibited by antitrust law.

Plaintiffs also incorrectly argue that "the number of lawsuits at issue is too few to qualify as a 'series.'" (Pl.'s Br. at 17.) The omitted portions of the cases cited by Plaintiffs only serve to highlight that the present facts are sufficient to establish a series of sham litigation. The *Hanover* court states: "[W]e do not set a minimum number requirement for the applicability of *California Motor* or find that four sham petitions will always support the use of *California Motor*." 806 F.3d at 181. Regardless, the *Hanover* court did find that four petitions were sufficient. *Hanover*, 806 F.3d at 181. Here, Plaintiffs' four lawsuits are similarly sufficient to implicate the series test.

In connection with its misstatement of the legal standard for serial sham litigation, Plaintiffs also raise a number of inapplicable arguments directed to the *PRE* "objective baseless" standard. First, Plaintiffs claim *Latisse I* cannot be objectively baseless because the lower court upheld the asserted '029 patent. (Pl.'s Br. at 12-13.) Plaintiffs cannot rely on that decision because the Federal Circuit reversed and held the patent invalid and not infringed—as a matter of law, the '029 patent claims were invalid. Even if Plaintiffs could rely on that decision, Akorn is not required to establish that each and every litigation within the series of sham litigations is

objectively baseless to succeed on its claim. *Hanover*, 806 F.3d at 182 (quoting *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354 (4th Cir. 2013)). Plaintiffs continue to assert substantially identical, related patents against Akorn despite Plaintiffs' 100% failure rate in the prior litigations, which illustrates the strong likelihood of sham litigation. Moreover, fact discovery is appropriate here to evaluate the sufficiency of these claims. *See In re Gabapentin*, 649 F. Supp. 2d at 363. Further, regardless of the timing of the filing of the *Latisse I* litigation, as of the date that Plaintiffs filed *Latisse III and IV*, Plaintiffs were well aware that the Federal Circuit had invalidated the *Latisse I* patents and the district court had held Allergan collaterally estopped from contesting the invalidity of the *Latisse II* patents in view of the Federal Circuit's decision in *Latisse I*.

Second, Plaintiffs misconstrue the law by claiming that *Latisse II* cannot be objectively baseless because "the district court rejected the argument that [it] was objectively baseless." (Pl.'s Br. at 14-15.) As a preliminary matter, Plaintiffs appear to acknowledge that the legal standard at issue in *Latisse II* was the "exceptional case" standard for attorney's fees, which is distinct from the "objectively baseless" standard required under *PRE* to evaluate a single sham litigation. *Octane Fitness LLC v. Icon Health and Fitness, Inc.*, 572 U.S. 545 (2014) (distinguishing the standard for "exceptional case" from the standard for sham litigation under *PRE*). Thus, contrary to Plaintiffs' statements, no court has evaluated whether the *Latisse II* claims were "objectively baseless" for the purposes of sham litigation. Moreover, as explained herein, when evaluating a series of sham litigations, the question is not whether one specific litigation is shown to be objectively baseless; Plaintiffs' whole course of conduct must be examined.

Similarly, Plaintiffs incorrectly allege the district court found *Latisse III* was not objectively baseless for the purposes of sham litigation. (Pl.'s Br. at 15.) Again, this is incorrect because the legal standard evaluated in *Latisse III* was the "exceptional case" standard for attorney's fees, and not the "objectively baseless" standard required under *PRE* for a single sham litigation. Surprisingly, although *Latisse II* and *III* had both evaluated the issue of whether the litigations were "exceptional" for the purposes of grating attorneys' fees, Plaintiffs assert without explanation that the standards are "identical" for purposes of *Latisse III* while acknowledging they are different for purposes of *Latisse II*. (*Id.*)

C. Akorn Has Sufficiently Pled That Plaintiffs' Have Engaged in Sham Litigation Supporting Its Actual Monopolization and Attempted Monopolization Counterclaims

Plaintiffs additionally ask the Court to dismiss Akorn's Fifth Counterclaim and the portion of Akorn's Sixth Counterclaim directed to harm caused by Plaintiffs' single sham litigation, by ignoring the well-pleaded allegations of Akorn's counterclaims and using an incorrect legal standard. The Court should deny Plaintiffs' motion.

Setting aside whether Plaintiffs engaged in a series of sham litigations, Akorn has pled sufficient facts to show, at least the instant matter, *Latisse IV* constitutes a sham under the standard for a single sham litigation because it concerns a patent that has substantially the same claims as at least one patent declared to be invalid by obviousness in *Latisse I*. *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) ("*PRE*"). Under the *PRE* standard, a lawsuit constitutes a sham petitioning that is not entitled to protection from antitrust scrutiny if it is "objectively baseless." Circumstantial evidence and reasonable inferences can be used to support a finding of sham litigation. *Hanover*, 806 F. 3d at 180-81.

Akorn's allegations sufficiently plead that the present case is objectively baseless. As set forth in Akorn's counterclaims, the '270 patent asserted in *Latisse IV* is a continuation of the

'029 patent invalidated in *Latisse I*. (*E.g.*, Akorn's Countercl. at ¶ 51.) The differences between the claims asserted in *Latisse IV and* those previously invalidated in *Latisse I, II, and III* do not materially alter the issue of invalidity. (*Id.* at ¶¶58-71; 106-115.) The '270 patent shares the same subject matter and parent application; a substantially identical specification; and substantially similar claims to the previously invalidated patent. (*Id.* at 19.) In *Latisse I*, the Federal Circuit found that the broad class of compounds allegedly covered by the claims of the '029 patent were invalid as obvious because the use of bimatoprost to grow hair was obvious in view of what was taught in the prior art. *See Allergan*, 754 F.3d at 962-66 (*Latisse I*); *Allergan*, 681 Fed. Appx. at 960-61, n. 5 (*Latisse III*) ("We previously found in [*Latisse I*] that it would have been obvious to use a topical application of a bimatoprost composition to grow eyelashes."). The asserted claims 22 and 30 of the '270 patent also cover the use of bimatoprost to grow hair. (Akorn's Countercl. at ¶¶51, 62.)[3] Claims 22 and 30 of the '270 patent are therefore also invalid as obvious, and Plaintiffs are collaterally estopped from asserting them based on the Federal Circuit's decision in *Latisse I*.

Regardless of whether Plaintiffs might have reasonably believed that the '270 patent was valid if evaluated *de novo*, Akorn has pleaded that Plaintiffs should have known as of the time of filing *Latisse IV* that at the very least, collateral estoppel would apply to preclude any good faith assertion of the claims of the '270 patent. Plaintiffs are clearly aware of the legal principle of collateral estoppel, as previous rulings in *Latisse II and III* held that Plaintiffs were collaterally

[3] Akorn has sufficiently pled this fact in its counterclaims. Moreover, Plaintiffs have admitted this fact in briefing submitted in a separate recent litigation. *Sandoz Inc. v. Duke Univ.*, Plaintiffs' Opp. to Mot. for Summary Judgment, No. 1:17-cv-823-CCE (M.D.N.C. Apr. 24, 2018), ECF No. 40 at 23 n.6.

estopped from asserting the litigated patents against Akorn based on the ruling in *Latisse I*.[4] Plaintiffs argue that *Latisse IV* is not a sham litigation because the lawsuit has "yet to be adjudicated." (Pl.'s Br. at 16.) But this argument willfully ignores the effect of collateral estoppel created by *Latisse I, II, and III*.

Even if a dispute remains regarding the objective reasonableness of Plaintiffs' alleged interpretation of the Federal Circuit's opinion and the '270 patent—which Akorn disagrees with—Akorn's counterclaim must survive the motion to dismiss because this analysis requires courts to accept all of Akorn's factual allegations as true for purposes of determining whether Akorn may be entitled to relief, under any reasonable reading of the counterclaims. *In re Gabapentin*, 649 F. Supp. 2d at 363-365 ("when the predicate facts of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law.").

Thus, this Court should deny Plaintiffs' motion to dismiss Akorn's Fourth and Sixth Counterclaims for monopolization and attempted monopolization based on a sham litigation.

There is no objectively reasonable basis for Plaintiffs to allege that the '270 patent claims are materially different from the previously invalidated claims of *Latisse I, II, or III* for the purposes of invalidity. Plaintiffs raise the implausible argument that "the '270 patent fixes the flaws the Federal Circuit found with the broader '029 patent claims invalidated in *Latisse I*." (Pl.'s Br. at 16.) However, this statement misconstrues both the Federal Circuit's opinion as well as the '270 patent claims and ignores the fact that Plaintiffs make the very same mistake for which the Federal Circuit expressly criticized the *Latisse I* district court and overturned the district court's ruling: it considers only the C-1 amide group of the claimed compounds and thus

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[4] Additionally, Plaintiffs cite the standard for collateral estoppel in its briefing (Pl.'s Br. at 14-15), although it mistakenly seeks to alter the legal standard to be more restrictive to Akorn and simultaneously blind to Plaintiffs' gamesmanship.

"fail[s] to take into account the full scope of the '029 patent claims." *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 962 (Fed. Cir. 2014). As admitted by Plaintiffs here, the Federal Circuit found the '029 patent claims obvious only "in part because they covered a wide range of prostaglandin compounds not limited to amides at the C-1 position." (Pl.'s Br. at 7.) Plaintiffs thus cannot overcome the weight of the prior art and the obviousness finding of *Latisse I* by addressing only one of the many problems with the'029 patent.

D. Akorn Has Sufficiently Pled Its Seventh Counterclaim for Unlawful Conspiracy To Monopolize

To establish conspiracy to monopolize, Akorn must establish: "(1) concerted action by the [counter-]defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action." *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005). At the pleading stage, Akorn is required only to identify facts, if construed as true, establish that relief is warranted. Because this is an antitrust claim, additional fact discovery is expected to provide further evaluation. *See, e.g.*, *In re Gabapentin*, 649 F. Supp. 2d at 347.

Here, Akorn has identified factual basis for each element in its counterclaims. There is a clear concerted action—agreement to enforce the licensed patents, including the '270 and '962 patents, joint filing of multiple patent infringement litigations against Akorn, including the instant litigation. (*E.g.*, Akorn's Countercl. at ¶¶ 209-212.) This concerted action produces the anticompetitive effects of fixing prices for Latisse while restraining trade by suppressing competition. (*Id.* at ¶¶ 213-214.) This concerted action was illegal at least because it sought to use sham litigation to restrain trade and maintain Plaintiffs' monopoly power. (*Id.* at ¶¶ 215, 219.) As a consequence, Akorn experienced the injury of, *inter alia*, increased cost of business

and forestalling, frustrating and preventing Akorn's ability to compete in the relevant market. (*Id.* at ¶ 218.)

Regardless, Plaintiffs' motion to dismiss does not address any of these elements. Instead, Plaintiffs' motion to dismiss is premised on the incorrect assertion that the mere relationship between Duke and Allergan as exclusive license and patent holder exempts Plaintiffs from conspiracy to monopolize under antitrust law. But to the contrary, courts have found that a patent owner and its exclusive licensee are indeed legally capable of entering a conspiracy. *See Townshend v. Rockwell Int'l Corp.*, No. C99-0400SBA, 2000 WL 433505, at *6 (N.D. Cal. Mar. 28, 2000) (holding patent owner and its exclusive licensee were "legally capable of entering a conspiracy"); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2018 WL 3973153, at *23 (D. Kan. Aug. 20, 2018) (holding patent owner and its exclusive licensee were "legally capable of entering a conspiracy"); *cf. Pecover v. Elecs. Arts Inc.*, 633 F. Supp. 2d 976, 983-44 (N.D. Cal. 2009) (holding that a series of agreements between a trademark holder and its exclusive licensees could be a conspiracy in violation of California antitrust law). Plaintiffs cite two cases to argue that patent holders and licensees are "incapable of conspiring," but neither establish a general rule blind to other fact discovery. For example, both *Shionogi* and *Levi* would require unified interests between the parties, which were evaluated through fact-specific inquiries *after* meaningful fact discovery had occurred.

Ultimately, "the question of capability to enter a conspiracy is a question of fact" and cannot be resolved by Plaintiffs' 12(b)(6) motion. *Townshend*, 2000 WL 433505, at *6 (denying motion to dismiss because questions of fact existed concerning whether "[defendants] are legally incapable of entering into a conspiracy" by virtue of exclusive license); *In re EpiPen*, 2018 WL

3973153, at *23 (denying motion to dismiss where plaintiffs alleged facts "capable of supporting a finding or inference that . . . Defendants are two separate entities engaged in concerted action to jointly advance their economic interests" even though defendants were licensor and licensee) (internal quotation marks omitted). Here, Akorn has pled numerous facts in support of its conspiracy to monopolize claim, and fact discovery is expected to further bolster these claims. (*See, e.g.*, Akorn's Countercl. ¶¶ 201-219.)

To the extent Plaintiffs argue that Akorn's Seventh Counterclaim should be dismissed for failing to allege a single sham or series of sham litigation, Plaintiffs' motion to dismiss should be denied for the reasons stated above.

E. Akorn's Eighth Counterclaim for Patent Misuse Should Not Be Dismissed

Patent misuse is a defense that allows a patent claim to be held unenforceable if the patentee impermissibly broadens the physical or temporal of the patent grant with an anticompetitive effect. *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc). "A plausible claim for patent misuse must, in turn, include an allegation that the patentee has impermissibly attempted to enlarge the scope of its patent monopoly." *Otsuka Pharm. Co., Ltd. v. Apotex Corp.*, 143 F. Supp. 3d 188, 196 (D.N.J. 2015).

This Court's *Apotex* decision regarding the sufficiency of allegations for patent misuse demonstrates the sufficiency of Akorn's counterclaims. In *Apotex*, the court compared patent misuse allegations directly to the patent misuse allegations in *Otsuka Pharm. Co. v. Torrent*, 118 F. Supp. 3d 646, 659 (D.N.J. 2015), where the allegations were insufficient to overcome a motion to dismiss. The dispositive factor—specific allegations of an attempt to expand the temporal or physical scope of the claims—is present in Akorn's counterclaims. Akorn alleges an expansion of the scope of the claims generally (Akorn's Countercl. at ¶¶ 228-231), including specific allegations of expanding the physical scope (*id.* at ¶ 230) and temporal scope (*id.* at ¶

231) of the asserted claims. These allegations were sufficient in *Otsuka v. Apotex*, and are sufficient here.

Plaintiffs assert that Akorn's pleading is insufficient because it does not sufficiently plead an expansion of the physical or temporal scope of the patent grant and because it relies on allegations of sham litigation. Plaintiffs appear to be arguing that because Akorn has not asserted a per se patent misuse violation (e.g., tying), then its claim is impossible. (Pl.'s Br. at 20.) This is not the correct standard. A practice constitutes patent misuse if it has the effect of extending the patentee's statutory rights and does so with an anticompetitive effect. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706 (Fed. Cir. 1992). "Any conduct that effectively extends the patentee's statutory rights with anticompetitive effect can qualify as misuse if the patentee sought to use the patent to secure more protection from competition than patent law intended to provide." *In re Gabapentin Patent Litig.*, 648 F. Supp. 2d 641, 655 (D.N.J. 2009) (denying motion to dismiss and allowing discovery for patent misuse affirmative defense). As required under the correct standard, Akorn has alleged that Plaintiffs have attempted to expand the scope of the patents causing an anticompetitive effect. (Akorn's Countercl. at ¶¶ 230-232, 238.) That is sufficient to defeat Plaintiffs' motion.

F. The Court Should Deny Plaintiffs' Motion to Strike Akorn's Antitrust and Misuse Affirmative Defenses

Plaintiffs ask that the Court take the extraordinary step of striking Akorn's affirmative defenses related to Plaintiffs' monopolizing conduct. Each of Akorn's identified affirmative defenses are proper. A finding by the Court that Plaintiffs have engaged in any one of the identified allegations—patent misuse, violating Section 2 of the Sherman Act through sham litigation, or violating Section 1 of the Sherman Act through a conspiracy to monopolize—may

result in the remedy of finding the particular patent unenforceable against Akorn, and bar Plaintiffs' requested remedies.

"An affirmative defense can be stricken 'only if the defense asserted could not possibly prevent recovery under any pleaded or inferable set of facts.'" *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F. Supp. 200, 218 (D.N.J. 1993) (quoting *Linker v. Custom-Bilt Machinery, Inc.*, 594 F. Supp. 894, 898 (E.D. Pa. 1984)). "If there is any doubt as to whether a matter in a pleading should be stricken, the doubt should be resolved in favor of the pleading." *United States v. Boston Scientific Neuromodulation Corp.*, No. 2:11-CV-1210 (SDW) (MCA), 2014 WL 4402118, at *3 (D.N.J. Sept. 4, 2014).

On their face, Akorn's Seventh, Eighth, and Ninth Affirmative Defenses give notice to Plaintiffs, particularly when the pleading as a whole is read, and so should survive Plaintiffs' unsupported motion to strike. Importantly, affirmative defenses are not governed by the *Twombly* standard, but instead by Rule 8(c)(1) that only requires notice of issues raised. *Malibu Media, LLC v. Does 1*, No. 12-2078, 2013 WL 1702549, at *2 (E.D. Pa. Mar. 6, 2013) (collecting cases). The cases relied upon by Plaintiffs involve allegations in affirmative defenses without accompanying counterclaims laying out detailed factual bases for each allegation. Here, Plaintiffs cannot plausible claim that they have not been provided sufficient notice of the bases for each of the three affirmative defenses.

Plaintiffs have not provided any specific argument why Akorn's affirmative defenses are impossible beyond the factual dispute over whether the present litigation is a sham or if Plaintiffs engaged in a series of sham litigations. As discussed above, this is a factual issue that must be resolved in Akorn's favor at this stage of the litigation. Plaintiffs' motion to strike is improper and should be denied.

V. THE COURT SHOULD DENY PLAINTIFFS' MOTION TO BIFURCATE

In the alternative to its motions to dismiss, Plaintiffs ask the court to bifurcate and stay Akorn's antitrust and patent misuse counterclaims. Plaintiffs' motion is fundamentally premised on the fact that this is a Hatch-Waxman litigation, but the present case is not typical. Akorn has obtained FDA approval for its product and there is no 30-month stay barring entry. Plaintiffs' motion would create unnecessary delay, duplicative discovery, and prejudice to Akorn. Moreover, there is a "general principle that a single trial tends to lessen the delay, expense and inconvenience to all parties." *Huertas*, 2009 WL 10697260 at *1. For that reason, the burden is on Plaintiffs to establish that bifurcation is necessary. *Id.* Here, Plaintiffs fail to meet this burden, and thus Plaintiffs' motion to bifurcate should be denied.

Plaintiffs attempt to sidestep its burden by incorrectly citing to a Federal Circuit case from 1986 to allege that bifurcation of antitrust and patent infringement claims is a "standard practice." (Pl.'s Br. at 23 (citing *Innotron*, 800 F.2d at 1084).) Plaintiffs wholly ignore the Third Circuit approach of condemning routine bifurcation of issues for trial. *Lis*, 579 F.2d at 824 ("[A] routine order of bifurcation . . . is a practice at odds with our requirement that discretion be exercised."). For example, the *Synopsys* court denied a motion to bifurcate patent infringement claims from antitrust claims, noting the evaluation must be "guided first and foremost by the merits of the case." *Synopsys, Inc. v. Magma Design Automation*, No. 05-cv-701(GMS), 2006 WL 1452803, at *4 (D. Del. 2006). While the movant in *Synopsys* had attempted to argue, like Plaintiffs here, that bifurcation was a general approach, the *Synopsys* court criticized the arguments as "contrary to the guiding principle enunciated in *Lis*." *Id.* The same analysis and conclusion in *Synopsys* should apply here.

A. Bifurcation and Stay of Akorn's Antitrust and Misuse Counterclaims and Defenses Would Be Inefficient and Prejudicial

Where the facts giving rise to the antitrust claims are also a "centerpiece" of the patent invalidity claims, courts have found "no efficiency in bifurcating the antitrust and patent claims because the evidentiary presentation of the cases would be "substantially duplicative." *Synopsys*, 2006 WL 1452803 at *4. The *Synopsys* court additionally rejected the argument that resolution of the patent claims could streamline subsequent adjudication of the antitrust claims, finding that "the minimum amount of time allocated to try this case does not decrease" and thus "it appears that a stay only has the potential to consume more of this court's valuable time." *Id.* at *5.

Here, there is significant overlap between the evidence and witnesses relevant in the antitrust and patent misuse issues as well as the patent infringement and validity, and separation of these issues would be highly inefficient. For example, Plaintiffs have not moved to bifurcate or stay either of Akorn's collateral estoppel counterclaim or affirmative defense. The factual analysis of the '270 patent and '029 patent that will be applied to determine whether collateral estoppel applies is closely tied to the timing and extent to which Plaintiffs' had knowledge that collateral estoppel would apply, which is relevant for Akorn's patent and misuse claims. There is no practical reason to separate the discovery of Plaintiffs' activities from Plaintiffs' knowledge of those same activities.

Bifurcation of these issues at trial would cause jury confusion, contrary to Plaintiffs' arguments. As noted above, the issues are largely overlapping and jurors are likely to be confused by any attempt to isolate and separate the issues. Additionally, there is efficiency in avoiding multiple trials and holding a greater number of jurors for a greater total amount of time. Plaintiffs attempt to argue that juror would be confused by the complex issues involved, but, as the *Synopsis* court opined while refuting this same argument, there is no reason to "pre-judge the

yet unnamed jurors by assuming they are unable to digest the facts and law in this case." *Synopsis*, 2006 WL 1452803 at *4. Additionally, the attorneys here will be able to present the issues clearly and succinctly, to promote efficiency. *See id.* ("Moreover, the court is confident that the experienced attorneys handling this case will craft cogent presentations to aid the jury in this process.") Bifurcation of discovery or trial would require multiple document collection efforts from identical sources and would require witnesses to be deposed twice and testify at two separate trials, creating significant burdens to them, the parties, and the Court. Duplicative discovery in the instant matter would mostly likely include:

- Collection and production of documents concerning prosecution of the '270 patent and decision-making involved;
- Collection and production of documents concerning invalidity or non-infringement evaluations performed by Plaintiffs;
- Collection and production of documents concerning communications between and among Plaintiffs;
- Depositions of named inventors and other individuals involved with the alleged invention claimed in the '270 patent and related patents;
- Deposition of Plaintiffs' witnesses having knowledge of marketing and business decisions concerning LATISSE®;
- Preparation of technical expert reports concerning the scope of the patent claims, invalidity and infringement, and/or knowledge thereof;
- Preparation of commercial expert reports concerning marketing and business decision-making and analyses;
- Depositions of technical experts concerning scope of the patent claims, invalidity and infringement, and/or knowledge thereof; and
- Depositions of commercial experts concerning marketing and business decision-making and analyses.

Staying and bifurcating discovery for the antitrust claims in this case will result in substantial duplication of discovery. At the least, Akorn should be allowed to proceed with discovery on all claims and defenses at this time, even if the trials are ultimately bifurcated.

B. Bifurcation and Stay of Akorn's Antitrust and Misuse Counterclaims and Defenses Would Prolong This Litigation and Prejudice Akorn

Bifurcation or stay of Akorn's antitrust and misuse counterclaims and defenses would unnecessarily delay resolution of the instant matter, causing prejudice to Akorn. Typically, Third Circuit courts find that "a piecemeal trial on separate issues involved in one suit is not necessarily in the interest of swift, economical and nonprejudicial justice." *Mellon v. Beecham Group PLC*, No. 86-2179, 1991 WL 16494, at *8 (D.N.J. Jan. 3, 1990). Plaintiffs provide no suggestion of the requested delay, but bifurcation or stay can be expected to delay final resolution of the proceedings by months, at a minimum, or even years. Akorn has waited for nearly eight years for resolution on its proposed generic product. Although the specific length of time is unclear, it is clear here that either bifurcation or a stay would further extend the distance to final resolution.

Moreover, bifurcation of the Antitrust and Patent Misuse affirmative defenses would actually have the potential of *prolonging* the resolution of the patent infringement claims, even if Plaintiffs could establish a prima facie case of infringement and validity—which it cannot. Bifurcating these defenses would prevent Akorn from fully litigating its defenses to patent infringement at the same time as the initial patent infringement and validity analysis; Akorn would be required to wait until an unknown later trial date to even begin presenting its affirmative defenses.

Plaintiffs argue that "adjudication of Plaintiffs' claim for infringement of the patent-in-suit has the potential to entirely moot Akorn's Antitrust and Misuse Counterclaims," based on

the incorrect assumption that the antitrust and misuse counterclaims cannot survive if Plaintiffs are able to raise credible arguments with respect to patent infringement. (Pl.'s Br. at 24.) This argument fails for two reasons. First, this allegation assumes that Plaintiffs will be able to overcome collateral estoppel, which it cannot. (*See supra* Section IV.C). Second, even if Plaintiffs are able to somehow raise credible arguments with respect to patent infringement, Plaintiffs' cannot escape antitrust liability simply by creating a façade. (*See supra* Section IV.B); *see also Hanover*, 806 F.3d at 180 ("Even if a small number of the petitions turn out to have some objective merit, that should not automatically immunize defendants from liability."). Thus, there is no judicial efficiency gained by a bifurcation or stay and the only meaningful consequence would be inefficiency and prejudice to Akorn.

Plaintiffs erroneously argue that Akorn will not be prejudiced by a stay of discovery simply because Akorn did not bring antitrust claims against Plaintiffs at an earlier date. As a preliminary nature, Plaintiffs cite to no case law suggesting such actions would waive Akorn's rights. Moreover, this argument ignores the prejudices against Akorn explained herein. Additionally, this argument ignores the most recent litigation filed by Plaintiffs and the sham nature of this litigation. (*See supra* Section IV.C). Plaintiffs provide no suggestion that Akorn could allege this litigation was a sham at any point in time earlier than Akorn's counterclaims.

C. Plaintiff's Motion to Bifurcate and Stay Is Premature

Plaintiffs argue that extensive discovery will be required for "antitrust-specific" issues, but fail to acknowledge the significant overlap in discovery and the efficiency gained by simultaneously pursing discovery. At this stage, it is unclear whether any of the issues Plaintiffs have identified as "antitrust-specific" will indeed be wholly distinct from relevant discovery directed to the patent infringement and/or invalidity issues. For example, the "relevant market" is the first of the three "antitrust-specific" issues identified by Plaintiffs. However, fact and

expert discovery directed to relevant market is commonly explored in patent infringement litigations in connection with, for example, the potential objective indicia of secondary considerations. At this early stage of litigation, it is unknown whether Plaintiffs will assert commercial success, as it did in *Latisse I*, and thus place the scope of the relevant market at issue.

In view of the high potential of overlapping discovery at this early stage in the case, the Court should deny Plaintiff's motion for bifurcation and stay.

D. Even if Bifurcation for Trial Is Granted, a Stay of Discovery Is Unwarranted

Regardless of whether the court grants bifurcation, a stay of discovery is inappropriate here, where the facts relevant to the patent infringement, antitrust, and misuse claims are so closely intertwined. *See, e.g.*, *Innotron*, 800 F.2d at 1078; *Novartis, et al. v. Watson Laboratories*, 2008 WL 10973750 (D.N.J. Oct. 28, 2008); *Enzo Life Scis., Inc. v. Digene Corp.*, No. 02-212-JJF, 2003 WL 21402512 (D. Del. June 10, 2003) (all declining to stay discovery on antitrust claims despite granting bifurcation). As noted above, the fact sources would likely require duplicative discovery if approached sequentially, creating extra expense and delay. Moreover, sequential discovery would likely create challenges in identifying the dividing line between relevant facts for patent infringement and the antitrust and misuse claims. Merely distinguishing the scope of collection or questioning for the first portion of the proceedings would likely create significant expense and burden to the parties. Instead, there will be greater efficiency in denying any stay of discovery and permitting expedient resolution of the complete dispute. *See, e.g.*, *Enzo*, 2003 WL 211402512 at *5 ("[T]he Court will deny the motion to stay because the Court finds that the interest in efficiently moving on with the resolution of the Counterclaims outweighs Enzo's concerns.").

VI. CONCLUSION

For the above stated reasons, Akorn respectfully requests that the Court deny Plaintiffs' motions to dismiss, or in the alternative, bifurcate and stay.

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s/ Lisa J. Rodriguez

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